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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/410,336	10/01/1999	SUSAN LOVE	18612-000410	6727

7590

07/16/2002

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Washington, DC 20001-4597

EXAMINER
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RAWLINGS, STEPHEN L

ART UNIT	PAPER NUMBER
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1642

DATE MAILED: 07/16/2002

19

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Advisory Action</b>	Application N . 09/410,336	Applicant(s) LOVE ET AL.	
	Examiner Stephen L. Rawlings, Ph.D.	Art Unit 1642	

**--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

THE REPLY FILED 11 June 2002 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

**PERIOD FOR REPLY** [check either a) or b)]

- a) ☐ The period for reply expires \_\_\_\_\_ months from the mailing date of the final rejection.
- b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection. ONLY CHECK THIS BOX WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1. ☐ A Notice of Appeal was filed on \_\_\_\_\_. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.
2. ☒ The proposed amendment(s) will not be entered because:
- (a) ☒ they raise new issues that would require further consideration and/or search (see NOTE below);
  - (b) ☒ they raise the issue of new matter (see Note below);
  - (c) ☒ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
  - (d) ☐ they present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: \_\_\_\_\_.

3. ☐ Applicant's reply has overcome the following rejection(s): \_\_\_\_\_.
4. ☐ Newly proposed or amended claim(s) \_\_\_\_\_ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
5. ☐ The a) ☐ affidavit, b) ☐ exhibit, or c) ☐ request for reconsideration has been considered but does NOT place the application in condition for allowance because: \_\_\_\_\_.
6. ☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.
7. ☒ For purposes of Appeal, the proposed amendment(s) a) ☒ will not be entered or b) ☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

The status of the claim(s) is (or will be) as follows:

Claim(s) allowed: \_\_\_\_\_.

Claim(s) objected to: \_\_\_\_\_.

Claim(s) rejected: 1-16.

Claim(s) withdrawn from consideration: 17-32.

8. ☐ The proposed drawing correction filed on \_\_\_\_\_ is a) ☐ approved or b) ☐ disapproved by the Examiner.
9. ☐ Note the attached Information Disclosure Statement(s) (PTO-1449) Paper No(s). \_\_\_\_\_.
10. ☒ Other: See the attached Note of Explanation

## NOTE OF EXPLANATION

1. The amendment filed June 11, 2002 (Paper No. 18) is acknowledged but will not be entered because the proposed amendment if entered, would raise new issues that would require further consideration and/or search, would raise the issue of new matter, and would not place the application in better form for appeal by materially reducing or simplifying the issues for appeal. If the proposed amendment were to have been entered, claims 1, 5, 9, and 13 would recite the step of allowing unbound portions of the delivered compound or identifying agent to be eliminated from said at least one duct. In addition, claims 9 and 13 recite a limitation requiring the lymph node involvement to be determined after said unbound portions of the delivered compound or identifying agent have exited said at least one breast duct. Thus, entry of the amendment would necessitate further consideration to determine whether or not the specification provides proper antecedent basis for recitation of these steps and limitations in the claims as the claims would be amended. Furthermore, if the proposed amendment were to have been entered, claims 1, 5, 9, and 13 would recite the step of allowing the delivered compound or identifying agent to bind to pre-malignant or malignant cells within the breast duct. Thus, entry of the amendment would necessitate further consideration to determine whether the inclusion of this step distinguishes the claimed method from the method of Hou, et al or an obviously modified method of Hou, et al to overcome the grounds of rejection under 35 USC §§ 102 and 103, respectively. It is apparent that Applicants believe that the recitation of this step would serve to distinguish the invention from the prior art. Nevertheless, at first glance, it would not appear that the inclusion of the step of allowing the compound to bind to the cells would not distinguish the claimed invention from the methods of the prior art, since the identifying agent of Hou, et al binds malignant and pre-malignant cells in the breast duct, albeit not exclusively.

Otherwise, it appears that Applicants have reiterated the arguments set forth in reply to the Office Action mailed March 9, 2001 (Paper No. 9), each of

which has been addressed in the Final Office Action mailed March 11, 2002 (Paper No. 17). Again, the substance and merit of Applicants' arguments have been carefully considered, but in view of the preponderance of evidence have not been found persuasive.

In particular, although Applicants have again argued that the phrase "cancer cell specific identifying agent" would be understood by the artisan of ordinary skill to mean an agent that binds only to cancerous cells and not to healthy cells, the Examiner disagrees for reasons already of record. To reiterate briefly, the specification teaches that the identifying agent used by the prior art would be suitably used in practicing the invention. Furthermore, although the specification teaches that a suitable identifying agent can comprise an antibody that binds erbB-2, as erbB-2 is not exclusively expressed by cancerous cells, the identifying agent would not be expected to bind exclusively to cancerous cells; thus, Applicants' narrow definition of the term "cancer cell specific" is not supported by the specification. It is believed that Applicants' other arguments have been adequately addressed in the previous Office Action and require no further comment.

2. Claims 1-31 are pending in the application. Claims 17-32 have been withdrawn from further consideration. Claims 1-16 remain rejected under the grounds set forth in the previous Office Actions. No claims are allowed.

3. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Stephen L. Rawlings, Ph.D. whose telephone number is (703) 305-3008. The examiner can normally be reached on Monday-Thursday, alternate Fridays, 8:00AM-5:30PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony C. Caputa, Ph.D. can be reached on (703) 308-3995. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242 for regular communications and (703) 308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.


Stephen L. Rawlings, Ph.D.

Examiner

Art Unit 1642

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July 12, 2002

  
ANTHONY J. PITA  
SUPERVISOR  
TECHNOLOGY CENTER 1600  
EXAMINER